UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

December 20, 2011

MEMORANDUM

Subject: Efficacy Review for Per-Ox; EPA File Symbol 833-U; DP Barcode: D393126.

From: Ibrahim Laniyan, Ph.D.
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12/23/11

To: Zebora Johnson / Marshall Swindell PM33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Regist

Applicant: Alex C. Fergusson, Inc.
5000 Letterkenny Road
Chambersburg, PA 17201

Formulation from the Label:

Active Ingredient	% by wt.
Hydrogen Peroxide	22.00 %
Peroxyacetic Acid	5.25 %
Inert Ingredients:	68.75 %
Total	100.00 %

I. BACKGROUND

The product, Per-Ox (EPA File Symbol 833-U), is a new product. The applicant requested to register the product for use as a sanitizer for industrial use only on previously cleaned hard, non-porous food contact surfaces. The registrant's representative's letter (dated June 15, 2011) stated that this is a me-too product with 5.25% peracetic acid and 22% hydrogen peroxide. The registrant provided product specific efficacy to support sanitizing claims. Additionally, the letter states that the "since the antimicrobial efficacy of hydrogen peroxide—peracetic acid based antimicrobial products is well established from the literature as well as from studies which have been previously submitted to EPA by registrants of such products; and for such products as are formulated only from hydrogen peroxide, the peracetic acid precursor, an acid catalyst, and water (as is the case for essentially all such antimicrobial products including Per-Ox Extreme) the antimicrobial efficacy is actually hydrogen peroxide and peracetic acid concentration specific but is not otherwise product specific since all such product have essentially the same formulation." The efficacy data was generated at ATS Labs, located at 1285 Corporate Center, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated June 15, 2011), EPA Form 8570-4 (Confidential Statement of Formula – dated 05/27/2011), EPA Form 8570-35 (Data Matrix), two studies (MRID Nos. 485569-03 and 485569-04), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II. USE DIRECTIONS

The proposed product is for industrial use only in dairies, wineries, breweries, beverage plants, meat, poultry processing plants, milk/dairy product processing plants, and eating establishments on eating, drinking, and food preparation utensils. The following directions were provided for the preparation and use of the product as described:

Sanitizing of Non-Porous Food Contact Surfaces: Remove gross particulate matter with warm water flush. Wash equipment with detergent or cleaning solution. Rinse equipment with potable water. Prepare solution by adding 1.0 to 1.7 fluid ounces of product 5 gallons potable water. This provides 90 to 153 ppm peroxyacetic acid and 378 to 644 ppm hydrogen peroxide. Fill closed system with diluted sanitizer solution and allows a contact time of 1 minute. If sanitizing against Listeria monocytogenes, use 1.2 to 1.7 fluid ounces of this product to 5 gallons potable water. This will provide 108 to 153 ppm of peroxyperacetic acid and 454 to 644 ppm of hydrogen peroxide. For open or not completely closed system, use a coarse spray, mop/wipe or flood technique to apply solution to the surface and allow contact time of 1 minute. Allow surface to drain thoroughly before resuming operation.

General Environmental Surfaces Sanitizing (Non-Food Contact): Remove gross filth with a cleaner or suitable detergent. Add 1 to 11 fluid ounces of product 16 gallons potable water to prepare a solution containing 28 to 311 ppm of peroxyacetic acid and 119 to 1302 ppm of hydrogen peroxide. Soak items in/with diluted solution using coarse spray, mop/wipe or flood techniques and allow contact time for at least 5 minutes. Allow items and/or surfaces to drain adequately or air dry.

Disinfection: Prepare disinfecting solution by adding 3.2 to 30 fluid ounces of the product to 5 gallons of potable water. This will provide 288 to 2707 ppm of peroxyacetic acid and 1211 to 11354 ppm hydrogen peroxide. Remove gross filth with from surfaces to be disinfected by

cleaning with a detergent or suitable cleaning product. Rinse with clean water. Apply by wiping, mopping, or as a coarse spray. Allow to soak for at least 10 minutes then air dry (Applications on food-contact surfaces require a sterile or potable water rinse following disinfection).

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces): Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/ml for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances. These Agency standards are presented the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID No. 485569-03, Germicidal and Detergent Sanitizing Action of Disinfectants against *Escherichia coli* and *Staphylococcus aureus* with Per-Ox, by Matthew Sathe. Study Completion Date—March 28, 2011. Project Number A10816.

This study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 1004, 1005, and 1006) of the product, Per-Ox, were tested using ATS Labs protocol no. AFC01122110.GDST (copy provided). Lot 1006 was the designated ≥ 60 days old at the time of testing. A 0.20 fl. oz/gallon was defined as 1.0 fluid ounce of the test substance in 5 gallons of filtered sterilized deionized water was prepared using 1.0 mL of the test substance in 640 mL of filter sterilized deionized water. The test organisms were transferred daily on Nutrient A agar slants. Bacterial growth washed from a 24±4 hour Nutrient Agar A slant for the test organism using 5.0 mL phosphate buffer dilution water. This growth suspension was aspirated and added to 99 mL of phosphate buffer dilution water. A 2.0 ml aliquot of the *E. coli* culture suspension was used to inoculated Nutrient Agar B contained in 6 French square bottles. A 2.0 ml aliquot of the *Staphylococcus aureus* culture suspension was used to inoculated Nutrient Agar B contained in 11 French square bottles. The bottles were tilted back and forth to distribute the inoculum and the excess inoculum was aspirated off. The bottles were incubated for 18-24 hours at 35-37°C. Following incubation, a 3.0 mL aliquot of phosphate buffer dilution water and approximately 15-20 sterile glass beads were added to each of the 6 French square bottles inoculated with *E.coli* to suspend the growth and to target 1 x 10^{10} CFU/mL Following incubation, a 1.5 mL aliquot of phosphate buffer dilution water and

approximately 15-20 beads were added to each of the 11 French square bottles inoculated with *Staphylococcus aureus* to suspend the growth. The suspension was removed from each bottle, filtered through sterile gauze pre-wetted with 1.00 mL sterile phosphate buffer dilution water and collected into a sterile tube. A spectrophotometric analysis was performed for each culture suspension using a wavelength of 620 nm. An aliquot (99.0 mL) of each lot of test substance at the concentration to be tested was added to duplicate 250-300 mL flasks and placed into a 25.0°C waterbath. The test substance was allowed to equilibrate for ≥ 20 minutes. A 1.0 mL aliquot of the culture suspension was added to each flask as follows:

- The flask was whirled and stopped just before the suspension was added;
- The test organism suspension was added midway between the center and edge of the surface with the tip of the pipette slightly immersed in the test solution.

A volume of 1.0 mL of the inoculated test substance was removed from each flask and added to 9 mL neutralizer at 30 seconds following the addition of the test organism suspension. After vortex mixing, four 1.0 mL and 0.1 mL aliquots of the neutralized test solution were transferred into individual sterile Petri dishes. A sufficient volume o f TGEA was transferred to each Petri dish and each dish was allowed to solidify. All subcultures and plates were incubated for 48±4 hours at 35-37°C. Plates were visually examined for growth. Controls included those for numbers, purity, sterility, viability, and neutralization confirmation.

V. RESULTS

MRID Number	Organism	Lot No.	Total No. Surviving (CFU/ml)	Parallel Control (CFU/ml)	Percent Reduction
30-Second Exposure Time					
485569-03	*Escherichia coli*	1004	$<1.0 \times 10^1$	8.6×10^7	>99.999
		1005	$<1.0 \times 10^1$	8.6×10^7	>99.999
		1006	$<1.0 \times 10^1$	8.6×10^7	>99.999
	Staphylococcus aureus	1004	3×10^2	9.6×10^7	>99.999
		1005	3.9×10^2	1.05×10^8	>99.999
		1006	7.5×10^2	1.05×10^8	99.999

VI. CONCLUSION

1. The submitted efficacy data (MRID No. 485569-03) supports the use of the product, Per-Ox, as food contact sanitizer against *Staphylococcus aureus* and *Escherichia coli* for a contact time of 30 seconds when prepared 0.20 fl. oz/gallon, on previously cleaned surface. Controls were acceptable as reported.

VII. LABEL

1. The proposed label claim is acceptable regarding the use of the product, Per-Ox, as a food contact sanitizer against *Staphylococcus aureus* and *Escherichia coli,* at a use rate of 1.0 to 1.7 fl. oz/ 5 gallons of potable water, for a contact time of 1 minute. **Acceptable efficacy data was provided to support the proposed claim**.

2. The proposed label claims are unacceptable regarding the use of the product, Per-Ox, as a disinfectant (any and all use sites), antimicrobial rinse of pre-cleaned or new returnable or non-returnable containers, fogging and sanitizer of non-food contact surfaces. **The referenced product formulations are not identical to the proposed product formulation. As a result product-specific efficacy data must be generated using the product, Per-Ox to support the proposed public health claims**.

3. The registrant must make the following revisions to the proposed label:

- Remove claims for all other microorganisms except *Staphylococcus aureus* and *Escherichia coli* as a sanitizing rinse.

- Remove all other claims except food contact surfaces sanitizing claims against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538)

- Add ATCC numbers to *Staphylococcus aureus* and *Escherichia coli*.